UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	**MDL No. 2804**
THIS DOCUMENT RELATES TO:	**Case No. 17-md-2804**
Track Three	**Judge Dan Aaron Polster**

PHARMACY DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE ANNA LEMBKE

This Court should exclude all or part of the opinion of Anna Lembke. In Track 1, Lembke, a medical doctor, opined that misleading and inaccurate information in opioid manufacturers' marketing and promotional materials influenced the opioid prescribing practices of physicians. Doc. 2549. This Court excluded portions of Lembke's proposed testimony, holding that although she was qualified to testify on matters "involv[ing] medical facts and science" that fall within her areas of expertise as "a medical expert in the scientific disciplines of psychiatry, addiction, and pain," she is unqualified to testify as an expert on marketing causation. Doc. 2549 at 11-12. This Court should continue to exclude those opinions, for the reasons set forth in its Track 1 Order. Doc. 2459.

In Track 3, Lembke has again attempted to offer opinions far beyond her expertise and qualifications, and her new opinions should be excluded. In Track 1, she admitted that she "wouldn't hold [herself] out as having expertise with respect to pharmac[ies.]" Ex. A, 4/24/2019 Track 1 Lembke Tr. at 271:10-13. Despite disclaiming any knowledge or expertise regarding the practice of pharmacy (and admittedly never having practiced, studied or worked in a pharmacy), she now suddenly offers expert opinions regarding pharmacies' national policies and dispensing practices, Ex. B, 5/28/2021 Track 3 Lembke Tr. at 131:12-25, based on having "reviewed a

number of articles" and "regulations."[1] This testimony is far outside her qualifications and expertise. Lembke should not be permitted to testify regarding whether pharmacists failed to exercise their corresponding responsibility and whether pharmacies failed to control against diversion.

In addition, the methodology she applies in considering these policies is unreliable. She has performed no analysis or investigation specific to Pharmacy Defendants' operations at their pharmacies in Lake and Trumbull County concerning dispensing, staffing or anything else. Instead, she interpreted national pharmacy policies at a high level and read articles generally discussing pharmacies and assumes, without any basis, that her conclusions apply to the specific pharmacies and pharmacists in Lake and Trumbull Counties at issue in this case.

Finally, her opinion that pharmacists dispensed prescriptions that lacked a legitimate medical purpose is internally contradictory, conflicts with her expert testimony regarding the effect of marketing on physicians' prescribing habits, and rests on a legally incorrect understanding of "legitimate medical purpose." Her concession—that prescribers were writing prescriptions in good faith in the exercise of medical judgment for medical purposes—confirms that these prescriptions were, in fact, written for a legitimate medical purpose. She should not be permitted to testify to the contrary.

[1] Ex. C, Expert Report of Anne Lembke at 148 ("Rite Aid's role in the opioid epidemic parallels those of Walmart, CVS and Walgreen, as described above. Policies ostensibly designed to control diversion were undermined by incentivized prescribing, understaffing, and poor enforcement, resulting in dispensing of controlled substances in violation of the CSA, and enforcement actions taken by the DEA."); (*id*. at 152) ("As with the other Pharmacy Defendants, no Rite-Aid policies called for the company to provide its pharmacists with analyses from their own data sets concerning controlled substance prescriptions or the doctors who prescribed them. This data was available to Rite Aid and should have been provided to the pharmacists, to help them to identify red flags of frequent, high volume, cocktail, or high dose prescribers.")

BACKGROUND

Anna Lembke is a medical doctor who is a Professor, Chief of the Addiction Medicine Dual Diagnosis Clinic, Medical Director of Addiction Medicine, and Program Director of the Addiction Medicine Fellowship, in the Department of Psychiatry and Behavioral Sciences at Stanford University School of Medicine. Ex. C, Expert Report of Anne Lembke at 1.

She is not a pharmacist, has never practiced pharmacy or dispensed an opioid medication, and never attended pharmacy school or otherwise trained as a pharmacist. Ex. B, 5/28/2021 Track 3 Lembke Tr. at 126:6-20. When asked what knowledge she has about pharmacy training, she replied: "I know that that have a certification – they have schooling, a certification process, but I don't know a whole lot more than that." *Id.* at 271:1-6. She "assumes[s]" pharmacists receive training in pharmacy school relevant to satisfying their corresponding responsibility but doesn't know for a fact whether they receive that training. *Id.* at 171:12-20. Her interactions with pharmacists were merely the typical interactions between pharmacists and medical doctors regarding the prescriptions written for patients in her care. "On any given clinic day I will have interactions with multiple pharmacies and pharmacists pertaining to prescriptions I have written or others have written for patients in my care." Ex. C, Expert Report of Anne Lembke at 6.

Lembke's testimony primarily concerns opioid marketing by manufacturers, explaining that manufacturers "misrepresented the risks and benefits of opioids," Doc. 2549 at 12, and created a "paradigm shift in opioid prescribing through misleading messaging about the safety and efficacy of prescription opioids." Ex. C, Expert Report of Anne Lembke at 8. Although she misleadingly (and falsely) implies that Pharmacy Defendants were also involved in marketing opioids as members of the expansive and undefined "Pharmaceutical Opioid Industry," her deposition made clear that her opinion truly concerns manufacturers' marketing efforts and that she has no basis to

suggest that Pharmacy Defendants were involved in marketing. *E.g.*, Ex. B, 5/28/2021 Track 3 Lembke Tr. at 74-76 (conceding that drug representatives work for manufacturers, that pharmacies were the target (not the source) of aggressive sales efforts, that opioid manufacturers were the entities that promoted drugs to doctors); *id.* at 186 (explaining that the marketing at the pharmacy counter was the use of manufacturer's coupons). She primarily opines that "the marketing of opioids by opioid manufacturers was a major factor in the creation of the opioid epidemic." *Id.* at 253:14-16.

In her Track 3 expert report and deposition, Lembke has attempted to stretch her expertise to new areas. Through reading articles and regulations, she purports to have now become an expert in pharmacy dispensing policies and practices. She also offers opinions—deeply misguided—that although prescribers were acting in good faith and believed they were prescribing for a legitimate medical purpose, prescriptions were not truly for a legitimate medical purpose if (in hindsight) she believes the prescription was improper.

ARGUMENT

I. Lembke Has No Expertise, Experience, or Qualifications that Would Permit Her to Offer Opinions Regarding the Practice of Pharmacy or Dispensing Policies

To testify as an expert, a witness must be qualified "by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Just as she did in Track 1, Lembke purports to offer expert opinions on subjects that are far outside her qualifications as a medical doctor. And just as in Track 1, this Court should exclude those portions of her opinion that are outside her expertise.

Lembke admittedly has no skill, experience, training, or education in the dispensing of opioids by pharmacists or other pharmacy practices. Ex. B, 5/28/2021 Track 3 Lembke Tr. at 126:6-24. In her Track 1 deposition, she admitted that she "wouldn't hold [herself] out as having expertise with respect to pharmacy[.]" Ex. A, 4/24/2019 Track 1 Lembke Tr. at 271:10-13. Two

years later, though, she has suddenly transformed herself into a pharmacy expert. Her opinions regarding pharmacy dispensing practices are based on research she conducted for this litigation. Here is how she described the "research" she conducted to form her opinion:

> I've reviewed a number of articles on the nature of a pharmacist's job, I've reviewed the regulations and the policies that the defendants put in place regarding the detection of red flags and a pharmacist's role in terms of misuse and diversion. I've researched lay press articles on whether or not pharmacists actually have the time and ability to do their due diligence around detecting and preventing red flags.

Ex. B, 5/28/2021 Track 3 Lembke Tr. at 131:17-25; *see also id.* 134:24-135:4 ("And all the research that you described in your report on the practice of pharmacy is research that you performed after the plaintiffs' lawyers asked you to express an opinion about the chain pharmacy defendants; is that right? A. The majority, yes.").

Lembke identifies nothing in her background that provides her any expertise in reading and interpreting "lay press articles" regarding pharmacists, an inadequate basis for expert testimony. *See In re Toy Asbestos*, No. 19-CV-00325-HSG, 2021 WL 1111226, at *3 (N.D. Cal. Mar. 23, 2021) ("[T]hat a person is well-read on a specific topic does not necessarily qualify her as an expert."). The California district court's analysis summarizes this situation perfectly: "If reading articles were sufficient on its own [to testify as an expert], any lay witness could qualify as an expert by summarizing and relaying such information for a given litigation." *Id.* Her training as a medical doctor does not make her any more qualified to testify as an expert on pharmacy practices "than a lay person who read the same articles." *United States v. Paul*, 175 F.3d 906, 912 (11th Cir. 1999)

Lembke's "expert opinion" is nothing more than acting as a conduit for hearsay from various articles while providing the imprimatur of expert testimony. *See, e.g.*, Ex. B, 5/28/2021 Track 3 Lembke Tr. at 155:3-7 ("I cite a number of different articles saying 'pharmacy staffing levels can threaten patients' lives' in the journal drug topics. Also, pharmacists' workload

contributes to errors in the 'Science Daily.'"); *id.* at 156:12-16 (quoting the Chicago Tribune). She does not purport to apply any expertise in reading or interpreting these articles—after all, she has no experience, background, or training that would permit her to do so. Instead, her "expert opinion" is simply unquestioningly repeating what various articles have stated.

Her opinion (and newfound expertise) is the product of litigation. Despite numerous articles that she has written regarding the opioid crisis, she claims to have mentioned pharmacies as a cause only once: a "brief mention in [her] book" that describes "access [to opioids] as a risk factor." *Id.* at 141:21-25, 140:1-7. She admits that before this lawsuit she never systematically "evaluated prescriptions that had been dispensed for opioid medications by a pharmacy to determine whether the pharmacist dispensed prescriptions without a legitimate medical purpose." *Id.* at 157:21-158:1.

Lembke has no expertise—no qualifications "by knowledge, skill, experience, training, or education," Fed. R. Evid. 702—that would permit her to offer a reliable opinion on the practice of pharmacy, pharmacy dispensing practices, or pharmacy operations, and she should not be permitted to serve as a conduit for hearsay. In Track 1, this Court found Seth Whitelaw, Plaintiffs' suspicious order monitoring expert, unqualified, in part, because before his work for Plaintiffs he "did not consider himself to be an expert on SOMS monitoring[.]" Doc. 2551. Likewise, before issuing her Track 3 expert report, Dr. Lembke did not consider herself to be a pharmacy expert. Her new opinions in Track 3 should be excluded.

II. Lembke's Methodology Is Unreliable Because She Failed to Consider Anything About Lake and Trumbull Counties.

Not only does Lembke lack expertise regarding pharmacy and dispensing policies and attempt merely to parrot various articles she has read, but the articles on which she bases her testimony do not concern Lake and Trumbull Counties.

Lembke did not perform any analysis whatsoever specific to dispensing or pharmacy operations in Lake and Trumbull Counties. Nor did she review any prescriptions at issue in the case. Ex. B, 5/28/2021 Track 3 Lembke Tr. at 136:5-12. Instead, her methodology was to review information regarding pharmacies generally and simply assume—with any investigation or analysis—that any conclusion she reached also fully applied to Lake and Trumbull Counties:

> Q. Anything specific to the pharmacists in Lake and Trumbull Counties?
>
> A. I don't have any reason to believe Lake and Trumbull Counties are an exception.

Id. at 175:18-21; *see also id.* 155:14-18 ("I don't have any evidence to suggest that what was being practiced nationally according to pharmacy defendants' chain drugstore policies would not be equally applied to pharmacies in Lake or Trumbull County."); *id.* at 158:20-24 ("I think that what was happening nationally was also happening in Lake and Trumbull County. I don't have any data to the contrary, but I can't identify a specific pharmacist by name in Lake or Trumbull County."); *id.* at 190:11-18 (admitting that she has conducted no "studies specific to Lake and Trumbull Counties as to individuals who developed opioid use disorder"); *id.* at 225:10-13 ("I have no reason to believe that pharmacies in Lake and Trumbull County are exempt from that, including pharmacies that are not named in this case.").

This approach is the opposite of reliable expert methodology. Rather than reviewing the data, applying expertise, and reaching an opinion regarding Lake and Trumbull Counties, Lembke reaches an opinion regarding national pharmacy practices (for which she has no expertise) and simply assumes that her opinion also covers Lake and Trumbull Counties. An expert's testimony must "res[t] on a reliable foundation and [be] relevant to the task at hand." *In re Modern Plastics Corp.*, 732 F. App'x 379, 386 (6th Cir. 2018) (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993)).

III. This Court Should Not Permit Lembke to Mislead the Jury By Using the Phrase "Pharmaceutical Opioid Industry" Or Otherwise Attributing Manufacturers' Marketing Activities to Pharmacy Defendants.

Even if this Court permits Lembke to testify, it should prevent her from misleading the jury by using the phrase "Pharmaceutical Opioid Industry" to falsely attribute the acts of opioid manufacturers to Pharmacy Defendants. The crux of Lembke's opinion is that "the marketing of opioids by opioid manufacturers was a major factor in the creation of the opioid epidemic." Ex. B, 5/28/2021 Track 3 Lembke Tr. at 253:14-16. Pharmacy Defendants did not engage in marketing of opioids. *E.g.*, *id.* at 74-76 (conceding that drug representatives work for manufacturers, that pharmacies were the target, not the source, of aggressive sales efforts, that opioid manufacturers were the entities that promoted drugs to doctors); *id.* at 186 (explaining that the only marketing at the pharmacy counter was the use of manufacturer's coupons); *id.* at 258:21-259:1 (conceding that CVS did not employ "drug reps").

Lembke should not be permitted to mislead the jury into believing that Pharmacy Defendants marketed opioids by referring to the manufacturers' activities as those of the "the opioid pharmaceutical industry." *E.g.*, *id.* at 69:16-19 (referring to "the opioid pharmaceutical industry that essentially both directly targeted doctors with an aggressive sales force and aggressive marketing campaign"). The risk of prejudice and misleading the jury from such testimony is extremely high. If Lembke testifies, this Court should require her to specify precisely which entities engaged in the specific activities she discusses and prevent her from inaccurately attributing the manufacturers' alleged conduct to Pharmacy Defendants through a vague and ill-defined phrase such as "pharmaceutical opioid industry."

IV. Lembke's Opinions About Whether Prescriptions Had a "Legitimate Medical Purpose" Are Unreliable, Internally Inconsistent, and Based on a Misunderstanding of "Legitimate Medical Purpose."

Finally, Lembke attempts to testify regarding whether prescriptions were dispensed for a "legitimate medical purpose," as required by 21 C.F.R. 1306.04. This testimony should be excluded because it is unreliable, unfounded, and far outside her realm of expertise.

Most of Lembke's testimony strongly supports Pharmacy Defendants. She testifies that due to misleading messages (promulgated by opioid manufacturers), prescribers were "duped" into overprescribing opioids. Ex. B, 5/28/2021 Track 3 Lembke Tr. at 22:4-17. She believes that the majority of doctors were "duped," including doctors in Lake and Trumbull County:

> Q. Were any doctors in Lake County or Trumbull County, Ohio, duped into prescribing opioid medications?
>
> A. Since the campaigns to mislead doctors were national campaigns, I have no reason to believe that the doctors in Lake and Trumbull County were an exception. So I think it's very likely that they too were duped into overprescribing

Id. at 22:22-23:4. In other words, she admits, doctors were prescribing opioids in good faith, based on the current medical knowledge and on the belief that there was a legitimate medical purpose for the prescription:

> Q. And in your view, were doctors acting in the belief that there was a legitimate medical purpose for prescribing opioids medications for pain?
>
> A. I do believe that the majority of doctors believed that they were prescribing for a legitimate medical purpose.

Id. at 29:10-16.

> Q. Is it your belief that a majority of the prescribers in Lake and Trumbull Counties, Ohio, believed that there was a legitimate medical purpose for prescribing opioids for pain?
>
> A. Because they were duped, I do believe that the national campaign spread to every corner of America and includes Lake and Trumbull Counties.

Id. at 30:2-8; *id.* at 53:21-23 ("[T]hey believed that they were writing opioid prescriptions for a legitimate medical purpose."); *id.* at 24:13-25:1 ("[I]t became commonly accepted for opioids to be first-line treatment for many different types of pain conditions[.]")

This testimony establishes that the majority of prescriptions were, in fact, issued for a "legitimate medical purpose" and that pharmacists thus complied with their corresponding responsibility under 1306.04 in dispensing them. Note the key word of the phrase: "purpose." What matters is the subjective "purpose" of the prescriber in writing the prescription. If a prescriber exercises medical judgment and writes the prescription for a legitimate medical purpose (*i.e,*. the treatment of the patient), then the prescription is—by definition—a prescription issued for a legitimate medical purpose. Such testimony supports Pharmacy Defendants, not Plaintiffs.

Lembke avoids this straightforward conclusion (and offers testimony in support of Plaintiffs) only by ignoring the plain meaning of the phrase "issued for a legitimate medical purpose" and substituting a new definition. According to Lembke, whether a prescription was written for a "legitimate medical purpose" has nothing to do with the prescriber's "purpose" in writing it. To be written for a "legitimate medical purpose," she contends, a prescription must be "informed by the science." *Id.* at 53:24-25. Thus, because (with the benefit of hindsight) she disagrees with prescribers' good-faith medical judgment, she intends to opine that prescriptions that prescribers actually issued for a "legitimate medical purpose" were not truly issued for a "legitimate medical purpose" as she interprets the phrase.

This unreliable opinion is far outside of Lembke's expertise and could do nothing but confuse the jury. "Purpose" means "purpose," not "informed by the science," correct, or desirable. Lembke cites to no source, no publication, and certainly no expertise for the proposition that a prescriber who writes a prescription in good faith based on the exercise of medical judgment and

consistent with the standard of care at the time could somehow have written a prescription that was "not for a legitimate medical purpose."

An error in allowing this testimony would undoubtedly require a new trial. The language of the regulation is plain and straightforward: What matters is the prescriber's good or bad faith, the "purpose" with which the prescription was written. *See* 21 C.F.R. 1306.04. A doctor who writes a prescription in good faith and in the exercise of medical judgment has written a prescription for a legitimate medical *purpose*, even if that judgment, in hindsight, appears to be incorrect and even if (as Lembke contends) that doctor was "duped" by the opioid manufacturers. Permitting Plaintiffs to argue or to introduce evidence (through Lembke or otherwise) that good-faith prescriptions written for a proper purpose were, nonetheless, not written for a legitimate medical purpose would go to the heart of the case, would be highly prejudicial, and would necessitate a new trial.

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For these reasons, Lembke's new Track 3 opinions should be excluded.

Dated: July 23, 2021

Respectfully submitted,

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